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TITLE 11
LEGISLATIVE RULES
BOARD OF MEDICINE

SERIES 5
BOARD OF MEDICINE RULES FOR DISPENSING OF LEGEND DRUGS BY PHYSICIANS AND PODIATRISTS

§11-5-1. General.

1.1. Scope. -- West Virginia Code §30-3-7(a)(1) authorizes the Board of Medicine to promulgate rules which are necessary to perform the duties and responsibilities of the Board, and West Virginia Code §60A-3-301 requires the Board of Medicine to collect a registration fee from licensees who dispense controlled substances.

1.2. Authority. -- W. Va. Code §30-3-7(a)(1); §60A-3-301.

1.3. Filing Date. -- May 3, 1989.

1.4. Effective Date. -- July 1, 1989.

§11-5-2. Definitions.

2.1. "The Board" means the West Virginia Board of Medicine.

2.2. "Dispensing physician" means a physician or podiatrist registered with the Board to dispense legend drugs within the scope of his or her practice.

2.3. "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by:

(a) A physician or podiatrist (or, in his presence, by his authorized agent), or

(b) The patient or research subject at the direction and in the presence of the physician or podiatrist.

2.4. "Controlled substance" means a drug that is classified by federal or state law in Schedules I, II, III, IV or V.

2.5. "Course of treatment" means the period of time necessary to effect a cure for an acute disease, or the period of time from one office visit until the next scheduled or anticipated office visit for a chronic disease.

2.6. "Dispense" means to deliver a legend drug to an ultimate user or research subject by or

pursuant to the lawful order of a physician or podiatrist, including the prescribing, packaging, labeling, administering or compounding necessary to prepare the drug for that delivery.

2.7. "Generic drug product" means a drug marketed without a trade name as a substitute for an innovator or previously patented pioneer drug.

2.8. "Legend drug" means a drug that may be dispensed under federal or state law only pursuant to the prescription of an authorized prescriber.

2.9. "Package insert" means the official labeling information sheet that accompanies a legend drug when it is distributed by the manufacturer.

2.10. "Professional samples" means complimentary drugs packaged and distributed in accordance with federal and state statutes and regulations and provided to a physician or podiatrist free of charge by manufacturers or distributors and distributed free of charge by the physician or podiatrist to his or her patients.

2.11. "Sale at retail" means dispensing legend drugs to persons other than current active patients of a physician during the course of treatment of such patients.

2.12. "Free clinic" means a clinic where medical and other health-related services are rendered at no charge.

2.13. "USP DI" means "United States Pharmacopeia Drug Information."

§11-5-3. General Rules for Dispensing Physicians.

3.1. Each physician or podiatrist who wishes to dispense legend drugs to patients shall register with the Board as a dispensing physician, on the form provided by the Board. The annual fee for registration as a dispensing physician shall be fifteen dollars ($15.00).

3.2. Physicians or podiatrists who are registered with the Board as dispensing physicians may dispense drugs to their own patients but not fill prescriptions written by other physicians or podiatrists, nor sell at retail such legend drugs. They may make reasonable charges for their services, including any legend drugs they may dispense, and may dispense amounts of drugs as they deem sufficient to a patient's course of treatment.

3.3. Physicians or podiatrists who are not registered with the Board as dispensing physicians may not dispense legend drugs. However, the following activities by a physician or podiatrist shall be exempt from the requirements of section 3 through 8 applicable to dispensing physicians:

(a) Legend drugs administered to the patient, which are not controlled substances when an appropriate record is made in the patient's chart.

(b) Professional samples distributed free of charge by a physician or podiatrist or certified physician assistant under his or her supervision to the patient when an appropriate record is made in the; patient's chart; or

(c) Legend drugs which are not controlled substances provided by free clinics or under West Virginia state authorized programs, including the medicaid, family planning, maternal and child health, and early and periodic screening and diagnosis and treatment programs: **Provided, however,** That all labeling provisions of section 8 shall be applicable except the requirements of section 8.3(a).

§11-5-4. Duties of Dispensing Physicians.

4.1. A dispensing physician may not delegate the dispensing function to another physician or podiatrist, nor to other office personnel. However, a dispensing physician may delegate nonjudgmental functions to supportive personnel, subject to the requirement that the dispensing physician must personally perform the following duties:

(a) Discuss with patients matters pertaining to the drug, its reasons for usage, and contraindications or answer questions regarding the dispensing physician's intent.

(b) Perform any other functions of any kind which require the knowledge, judgment, ability or skill of a dispensing physician.

4.2. A dispensing physician who is the supervising physician for a "Type A" Physician Assistant may delegate the dispensing function to that "Type A" Physician Assistant. A "Type A" Physician Assistant must follow all rules applicable to the dispensing physician. A "Type A' Physician Assistant may dispense only those legend drugs that he or she is authorized to prescribe. A "Type A" Physician Assistant may dispense legend drugs to those patients for whom the "Type A" Physician Assistant has prescribed the legend drugs at the direction of the supervising physician, but may not dispense legend drugs to patients for whom the supervising physician has prescribed legend drugs.

4.3. A dispensing physician must have access to reference books relating to the dispensing of medication, including the most recent edition of USP DI.

4.4. A dispensing physician must have immediate access to the package insert, or its equivalent, for every legend drug dispensed to patients.

4.5. A dispensing physician must maintain equipment necessary for the dispensing of legend drugs, including a typewriter or computer and

(a) For solid oral dosage forms, two (2) pill counting trays and two (2) spatulas;

(b) For liquid oral dosage forms (including antibiotic powders for reconstitution), distilled water, two (2) glass stirring rods, two (2) glass or plastic funnels, filter paper and one 1/2cc to 500cc graduate.

4.6. A dispensing physician must maintain a dispensing area, where all stock quantities of legend drugs maintained for dispensing to patients must be stored under conditions that meet USP criteria as published in USP DI, to prevent deterioration. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the dispensing physician is not present in the office.

§11-5-5. Sale at Retail Prohibited.

5.1. The sale at retail of legend drugs by dispensing physicians is prohibited.

§11-5-6. Freedom of Choice.

6.1. Every patient has the right to receive a written prescription as an alternative to having legend drugs dispensed by a dispensing physician.

6.2. A sign no smaller than 8 1/2" by 11" shall be posted in a conspicuous place in the office of every dispensing physician, which must include the following language: "Every patient has the right to receive a written prescription as an alternative to having legend drugs dispensed by your physician."

6.3. If a physician charges for dispensing legend drugs, a charge for legend drugs shall be separately listed on the patient's bill and the patient shall be informed of the separate charge for said legend drug prior to having the prescription filled by the physician.

6.4. When a patient receives a generic drug product from a dispensing physician, the patient shall be told that a generic drug product is being dispensed.

§11-5-7. Packaging.

7.1. Dispensing physicians shall package legend drugs in appropriate containers. The Board recognizes the United States Pharmacopeia standards as expressed in USP DI as the standard reference for determining legend drug packaging requirements.

(a) If a legend drug is susceptible to light, it must be packaged in a light-resistant container, as specified in USP DI.

(b) If a legend drug is susceptible to moisture, it must be packaged either in a well-closed container or in a tight container, as specified in USP DI.

(c) Paper or plastic bags, boxes or envelopes do not meet packaging requirements for legend drugs and should not be used.

7.2. All legend drugs must be dispensed in containers that comply with the child-resistant packaging standards mandated by the Federal Poison Prevention Packaging Act of 1970 (PPPA).

(a) The Board recognizes that under the PPPA child-resistant packaging is to be the rule and not the exception.

(b) The Board further recognizes that under the PPPA there are specific exceptions to the requirement of child-resistant packaging.

(1) If the patient receiving the legend drug requests, or if the prescriber determines that it is appropriate, a legend drug may be dispensed in a noncomplying container that is not child-resistant.

(2) The following legend drugs are exempt from the requirement of the PPPA:

(A) Cyclically administered oral contraceptives in manufacturer's memory-aid dispenser packages.

(B) Sublingual dosage forms of nitroglycerin.

(C) Sublingual and chewable forms of isosorbide dinitrate in dosage unit containing10mg or less.

(D) Aqueous solutions and tablets containing sodium fluoride with no more than 265mg / package.

(E) Betamethasone in tablet form in packages containing not more than 12.6mg of the drug.

(F) Mebendazole in tablet form in packages containing not more than 600mg of the drug.

(G) Methylprednisolone in tablet form in packages containing not more than 84mg of the drug.

(H) Colestipol in powder form in packages containing not more than 5g of the drug.

(I) Erythromycin ethylsuccinate in tablet form, each tablet containing no more than 250mg of the drug and dispensed in packages of no more than 80 tablets.

(J) Erythromycin ethylsuccinate granules for oral suspension in packages containing not more than 8g of the drug.

(K) Anhydrous cholestyramine (chloride salt of a basic anion-exchange resin) in powder form.

(L) Individually packaged effervescent potassium supplement tablets containing not more than 50mgEq of potassium per tablet.

(M) Pancrelipase preparations in tablet, capsule or powdered form.

§11-5-8. Labeling.

8.1. Each legend drug dispensed by a dispensing physician must be packaged in its own separate container and labeled with its own specific directions.

8.2. Labels must be machine-made or printed legibly.

8.3. Legend drugs that are not classified as controlled substances must be packaged in a container labeled with the following information:

(a) Dispensing physician's name, address and telephone number.

(b) Patient's name

(c) Date dispensed

(d) Name of drug

(e) Full directions for use

(f) Appropriate ancillary label(s), such as "Keep Refrigerated" or "This drug may cause drowsiness."

8.4. Legend drugs that are classified as controlled substances must be labeled with the above information (8.3, a-f) in addition to the following statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

8.5. The directions "Take as directed" are permitted only as an exception to the general rule requiring full directions for use, because they are not specific and can lead to patient confusion and error.

8.6. If a generic drug product is dispensed, the container shall be labeled with the generic name of the drug and the name of the manufacturer or distributor of the generic drug product. The container may not be labeled with a brand name unless the product dispensed is actually the brand name product.

§11-5-9. Dispensing Records.

9.1. A dispensing physician must maintain records that are available for inspection.

9.2. Patient records must facilitate an audit trail for each patient to whom legend drugs are dispensed. They may be maintained either in a patient's chart or in an equivalent but separate patient medication record.

9.3. Daily records must facilitate an audit trail for each day on which scheduled controlled substances are dispensed. They may be maintained in a daily log or in a file of prescriptions.

(a) Daily records of dispensed Schedule II controlled substances must be maintained in a separate daily log or file of prescriptions, apart from all other records.

(b) Daily records of dispensed Schedule III, IV and V controlled substances may be maintained either in another separate daily log or in a file of prescriptions.

9.4. For each legend drug dispensed, both patient records and daily records shall include:

(a) Patient's name,

(b) Drug name and strength,

(c) Quantity dispensed,

(d) Directions for use.

§11-5-10. Other Legal Authority.

10.1. Dispensing physicians must comply with all federal and state laws applicable to dispensing physicians.

§11-5-11. Disciplinary Action.

11.1. Violation of these rules concerning dispensing physicians constitute unprofessional conduct and subjects the violator to disciplinary action by the Board under the provisions of West Virginia Code §30-3-14.